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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,549	08/18/2003	Richard Frederick Dechant		1961

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EXAMINER	
GRAFFEO, MICHEL	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,549	DECHANT, RICHARD FREDERICK	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 12-9-05
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claim 2 is pending and examined.

Applicant has amended claim 1 and provided arguments for the patentability of claim 1 in the response filed 8 November 2005.

In light of Applicant's Amendment dated 8 November 2005, the rejection to claim 1 under 35 USC §103 has been withdrawn to the extent that the Shefer et al. reference does not, by itself, make obvious the claimed invention. Any rejection not specifically stated in this Office Action has been withdrawn.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim in the response filed 8 November 2005 been renumbered as claim 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of visible tumors via direct application of the composition as well as precancerous cells using camphor and resorcinol or mixtures thereof and a chemotherapeutic agent sulfathiazole (as defined by the prior art but not the instant specification), does not reasonably provide enablement for the treatment of all carcinomas, melanomas, susceptible forms of cancer etc. Nor is the claim enabled for treating such cancers via contact between sublingual or rectal tissues and the composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims particularly because absent some evidence of functionality of the claimed composition, evidence supporting, for example, presence of a cancer, treatment and then absence or beneficial change in the cancer and a comparison or control, the utility standard cannot be met.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

1) the nature of the invention;
2) the breadth of the claims;

3) the predictability or unpredictability of the art based on the skill of one in the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples; and
6) the quantity of experimentation necessary for one skilled in the art based on the state of the art;
7) the state of the prior art; and ,
8) the relative skill of those skilled in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1) the nature of the invention; the claims are directed to a method of treating carcinomas , melanomas, colorectal cancer, ovarian cancer and other susceptible forms of cancer comprising the application of a composition comprising resorcinol, camphor, sulfathiazole and propylene glycol.

2) the breadth of the claims; the scope of the claims includes the treatment of the above forms of cancer via applying the composition to rectal and sublingual tissue.

3) the predictability or unpredictability of the art; the applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the anticancer effects of the instant composition. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Therefore, since treatments for all cancers described above are not known,

especially the treatment of all the claimed cancers via sublingual and rectal tissues are not shown or taught in the art per se, the amount of predictability in the art is lacking and therefore the enablement.

Gura (Science, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed composition could be predictably used as an anti-cancer agent for cancer therapeutic strategies as inferred by the claim and as contemplated by the specification. Further, the refractory nature of cancer to drugs is well known in the art. Jain (Sci. Am., 1994, 271:58-65) teaches that tumors resist penetration by drugs (p.58, col 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited and further teaches that

it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (p. 36, col 2). It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed composition could be predictably used as an anti-cancer agent for cancer therapeutic strategies as inferred by the claim and as contemplated by the specification. In addition, anti-tumor agents must accomplish several tasks to be effective. They must be delivered into the circulation that supplies the tumor and interact at the proper site of action and must do so at a sufficient concentration and for a sufficient period of time. Also, the target cell must not have an alternate means of survival despite action at the proper site for the drug. In addition variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. The agent may be inactivated *in vivo* before producing a sufficient effect, for example, by degradation, immunological activation or due to an inherently short half life of the agent. In addition, the agent may not otherwise reach the target because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the agent has no effect, circulation into the target area may be insufficient to carry the agent and a large enough

local concentration may not be established. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the claimed invention would function as inferred and contemplated by the specification with a reasonable expectation of success. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

4) the amount of direction or guidance presented; the instant application provides no guidance for the treatment of cancer via contacting the claimed composition with sublingual and rectal tissues.

5) the presence or absence of working examples; there are no working examples provided in the instant application.

6) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention and the unpredictability of the route of administration, and the lack of working examples regarding the activity as claimed, one skilled in the art

would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-6, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application No 2003/0175328 to Shefer et al. in view of Camphor Monograph (Merck Index, 13th Edition, 2001 Monograph 01739), Resorcinol Monograph (Merck Index, 13th Edition, 2001 Monograph 08240) and Sulfathiazole Monograph (Merck

Index, 13th Edition, 2001 Monograph 09031) and further in view of the Propylene glycol Monograph (Merck Index, 13th Edition, 2001 Monograph 07947).

Shefer et al. teach a method of topically treating (see Abstract) precancerous cells (see paragraph 24) comprising camphor and resorcinol or mixtures thereof (see paragraph 39) and a chemotherapeutic agent such as sulfathiazole (see paragraph 52) and a solubilzer such as propylene glycol (see paragraph 21) wherein the active agent is present in an amount of from 0.001% to about 80%.

Shefer et al. do not specifically teach the application of the composition via a cotton swab for 4-5 minutes.

Shefer et al. teach the application of the composition for a recommended treatment period (see paragraph 65) and also teach topical administration of the composition. Thus, one of skill in the art would have found it obvious to optimize the treatment duration and method of application. Additionally, Shefer et al. do not specifically recite a method of treating cancer, but yet teach a method of treating precancerous tissues. Nonetheless, the composition admittedly comprises a chemotherapeutic drug, sulfathiazole, which ultimately suggests its use as an anticancer composition.

The camphor monograph teaches that camphor is useful as a topical antiseptic agent (see Therapeutic Category).

The resorcinol monograph teaches that camphor is useful as a topical antiseptic agent (see Therapeutic Category).

The sulfathizazole monograph teaches that camphor is useful as an antibacterial agent (see Therapeutic Category).

The references do not expressly teach that the combination of the agents herein are useful in a composition. The references do not expressly teach that the amount of each agent: camphor, resorcinol and sulfathiazole are used in any particular amounts. Nonetheless, one of ordinary skill in the art would have appreciated the obviousness of the particular agent amounts through routine optimization. Further, the references do not expressly teach the employment of propylene glycol in the composition.

The propylene glycol monograph teaches that propylene glycol is useful as a solvent in pharmaceuticals (see Use section).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the agents herein into a composition because camphor, resorcinol and sulfathiazole are known in the art to be useful as an anti-microbial agent. One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. In other words, Shefer et al. combined with the Merck monographs teach a method of treating cancer comprising the claimed ingredients. One of ordinary skill in the art would have been motivated to combine the references because combining agents which are known to be useful as antiseptics individually into a single composition useful for the very same purpose is prima facie obvious. See In re Kerkhoven 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very

same purpose, the idea of combining camphor, resorcinol and sulfathiazole flows logically from their having been individually taught in the prior art. Further, one of ordinary skill in the art would have found it obvious to combine Shefer et al. with the Merck monographs because Shefer et al. teach a composition comprising each of the ingredients and the Merck monographs teach the therapeutic category common to each. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Response to Arguments

Applicant's arguments, see Response, filed 8 November 2005, with respect to claim 1 and the rejection under 35 USC §103 have been fully considered and are persuasive. The rejection under 35 USC §103 has been withdrawn to the extent noted above.

Applicant's arguments filed 8 November 2005 have been fully considered but they are not persuasive to the extent that Applicant has not provided sufficient evidence to enable one of ordinary skill in the art to make and use the invention as claimed. Applicant is required to provide some credible evidence as to the claimed composition's utility. Absent some evidence of functionality of the claimed composition, evidence supporting, for example, presence of a cancer, treatment and then absence or beneficial change in the cancer and a comparison or control, the utility standard cannot be met. In other words, to overcome the current rejections, Applicant must demonstrate

either that the invention as claimed has greater than expected results (see MPEP 716.02) or that the amounts not claimed but disclosed in Shefer et al. do not function as claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3 January 2006
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